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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 526 and 556

Intramammary Dosage Form New Animal Drugs; Pirlimycin Hydrochloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provides for use of a sterile solution of pirlimycin hydrochloride for intramammary treatment of clinical and subclinical staphylococcal and streptococcal mastitis in lactating dairy cows, for reduction in the preslaughter withdrawal period, and for revision of the milk discard statement in labeling to state the milk discard time only (i.e., to remove reference to the number of milkings).

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplemental application to NADA 141–036 that provides for use of PIRSUE® (pirlimycin hydrochloride) Sterile Solution for intramammary treatment of clinical and subclinical mastitis in lactating dairy cattle caused by *Staphylococcus* species, such as *Staphylococcus aureus*; and *Streptococcus* species, such as *Streptococcus agalactiae, Streptococcus dysgalactiae,* and *Streptococcus uberis;* for reduction in the preslaughter withdrawal period from 28 days to 9 days; and for revision of the milk discard statement in labeling to state the 36-hour milk discard time

only (i.e., to remove reference to the number of milkings). The supplemental NADA is approved as of September 7, 2000, and the regulations are amended in 21 CFR 526.1810 to reflect the approval.

In addition, the regulations are amended in (21 CFR 556.515) to add the previously established acceptable daily intake for total residues of pirlimycin, to add a tolerance for residues of pirlimycin in cattle muscle and, editorially, to reflect current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning September 7, 2000, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new formulation for which the supplemental application was approved.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 526

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 526 and 556 are amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORM

1. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 526.1810 [Amended.]

2. Section 526.1810 *Pirlimycin hydrochloride aqueous gel* is amended by removing ''aqueous gel'' from the section heading, by removing ''(three milkings)'' from the first sentence in paragraph (d)(3), by removing ''28'' from the second sentence in paragraph (d)(3) and by adding in its place ''9'', and by removing the third sentence of paragraph (d)(3).

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

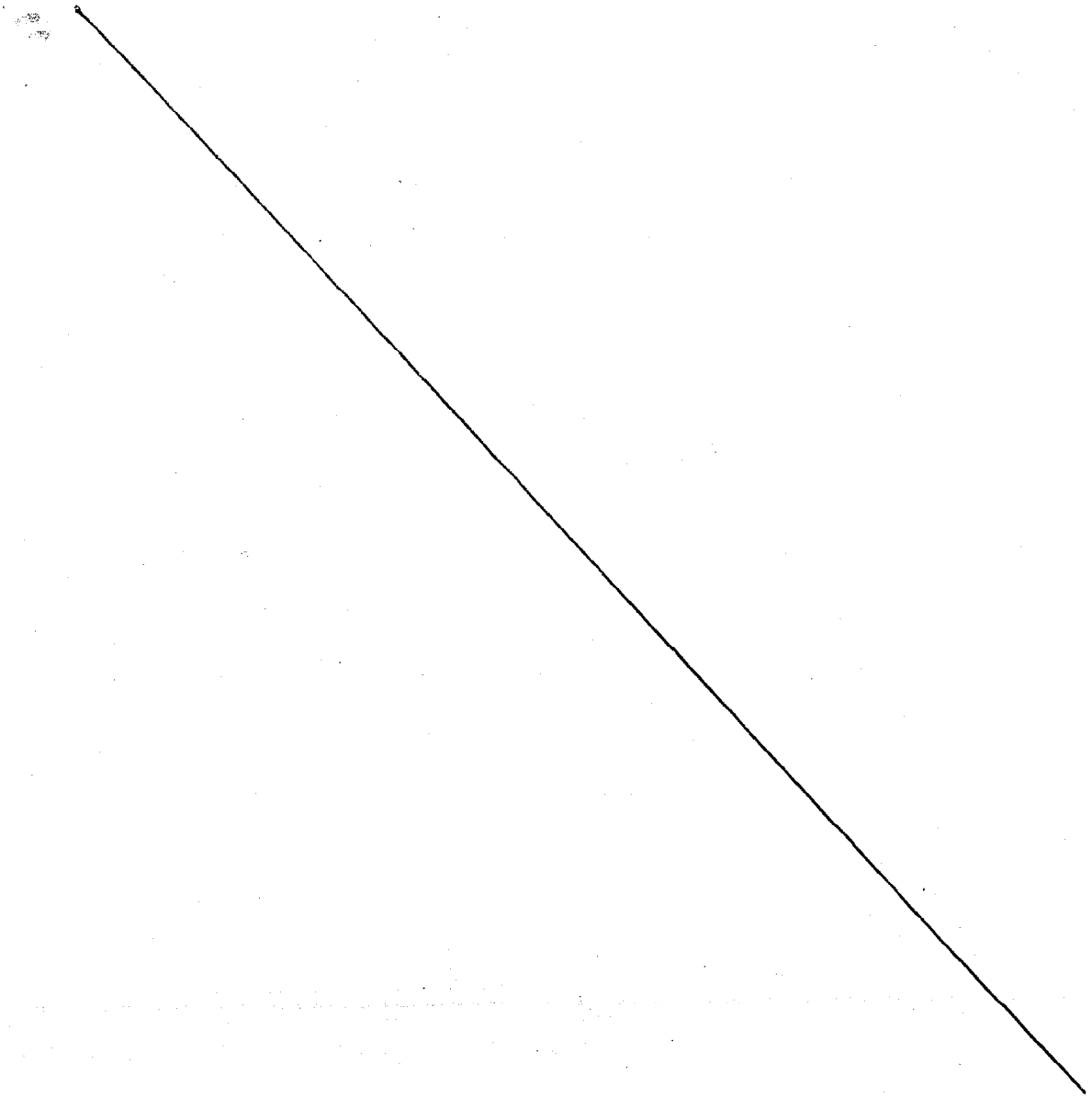
Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.515 is revised to read as follows:

§ 556.515 Pirlimycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of pirlimycin is 0.01 milligrams per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent pirlimycin (the marker residue) is 0.5 part per million (ppm).



(ii) *Muscle*. The tolerance for parent pirlimycin (the marker residue) is 0.3 ppm.

(iii) *Milk*. The tolerance for parent pirlimycin (the marker residue in cattle milk) is 0.4 ppm.

(2) [Reserved]

Dated: 10/6/00
October 6, 2000

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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